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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,943	02/22/2002	Dean Sadat-Aalae	00537-191002	3207
37903	7590	01/08/2004	EXAMINER	
DAWN JANELLE AT BIOMEASURE INC. 27 MAPLE STREET MILFORD, MA 01757			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,943

Applicant(s)

SADAT-AALAE ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 6 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

1. The disclosure is objected to because of the following informalities: At pages 14 and 17, the status of the U.S. patent applications should be updated. This includes indicating those applications which are now abandoned. Appropriate correction is required.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-5, 7, 8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/24807. The WO Patent Application '807 teaches compounds of the formula set forth in claim 1 in which residue A⁶ can be Abu, beta-Ala, Gaba, or Val (see claim 4). The WO Patent Application '807 also teaches a specific compound at page 38, line 23, which differs from Applicants' compound at claim 3, line 5, in that the compound of the reference has an Abu rather than a Gaba residue at the position corresponding to A⁶, and teaches a specific compound at page 39, line 31, which differs from Applicants' compounds of claim 4 in that the compound of the reference has a Val rather than a Gaba or beta-Ala residue at the position corresponding to A⁶. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute a Gaba residue for the Abu residue in the WO Patent Application '807's compound at page 38, line 23, because Applicants' claimed compounds are generically encompassed by the formula of the WO Patent Application '807's claim 1; because the WO Patent Application '807 discloses these residues to be equivalents at this position; because the Gaba and Abu residues are isomers of one another; and because the resultant somatostatin analogs have the same imaging utility disclosed by the WO Patent Application '807. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute a Gaba or beta-Ala residue for the Val residue in

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the WO Patent Application '807's compound at page 39, line 31, because Applicants' claimed compounds are generically encompassed by the formula of the WO Patent Application '807's claim 1; because the WO Patent Application '807 discloses these residues to be equivalents at this position; and because the resultant somatostatin analogs have the same imaging utility disclosed by the WO Patent Application '807. The WO Patent Application '807 teaches that its somatostatin analogs can be used to image cells in vitro and in vivo (see, e.g., page 24, lines 18-23). Applicants have stated in their specification that their claimed compounds have unexpected agonist as opposed to antagonist activities (see, e.g., page 2, lines 14-22, of Applicants' specification). However, in the absence of a probative comparison of the closest prior art compounds of the WO Patent Application '807 and of Applicants' claimed compounds in the same assay, Applicants' statement in and of itself can not be relied upon to rebut the prima facie case of obviousness set forth above. No comparative evidence commensurate in scope with Applicants' claims is present in the specification. With respect to instant claim 8, the WO Patent Application '807 does not teach using its somatostatin analogs to treat cancer cachexia or decreasing body weight. However, the WO Patent Application '807 does disclose that its compounds are useful for promoting the release of growth hormone (see, e.g., page 25, lines 22-25). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the somatostatin analogs of the WO Patent Application '807 to humans or other animals with cancer cachexia or decreasing body weight because the somatostatin analogs' disclosed ability to promote growth hormone release would have been expected to be useful in counteracting cancer cachexia and decreasing body weight, and because

it is routine to use somatostatin antagonists for the same purposes that other somatostatin antagonists are used.

4. Applicant's arguments filed November 14, 2003 have been fully considered but they are not persuasive.

The declaration by Taylor filed November 14, 2003 has been carefully considered but is not deemed to rebut the prima facie case of obviousness. The declaration does not establish unexpected results for the claimed invention because the experiments set forth in the declaration are not commensurate in scope with Applicants' claims, and because the experiments do not include a probative comparison with the closest prior art of record. The experiments set forth in the declaration are not commensurate in scope with Applicants' claims because only two compounds are tested for agonist activity. This is not sufficient for one of ordinary skill in the art to assume that any unexpected results extend throughout the range of claimed compounds. The test for agonist activity must also include at least the compound recited at Applicants' claim 3, line 5. (The examiner assumes that the declaration at page 2, section 6, line 6, misnames the compound of Example 1. Note the recitation of "Ala" rather than " β -Ala".) The declaration does not perform its agonist measuring assays using the closest compounds of the prior art, i.e. the compounds named at page 38, line 23, and page 39, line 31, of the WO Patent Application 98/24807. The examiner agrees that agonist and antagonist activities are measured using different assays. However, the issue here is whether the specific compounds of the WO Patent Application '807 exhibit any agonist activity. This can be determined as readily as the activity of Applicants' claimed compounds can be determined, i.e. by performing Applicants' disclosed agonist assay using the specific compounds of the WO Patent Application '807. In the absence

of such a direct comparison, it is not possible to conclude that Applicants' compounds have some activity not possessed by the compounds of the prior art. Given that the declaration shows that Applicants' compounds activate the somatostatin receptor to a degree significantly less than does the somatostatin control (29% and 25% vs. 100%), it is questioned as to whether it would be more accurate to characterize Applicants' compounds as partial agonists rather than as full agonists (see the definition of "partial agonist" in Stenesh, Dictionary Of Biochemistry And Molecular Biology, page 347, copy provided). The possibility of the same compound exhibiting both agonistic and antagonistic properties, depending upon the assay and assay conditions, underscores the need to make comparisons of both the prior art compounds and the claimed compounds using the same assay under the same conditions.

In section 6, the Declarant provides evidence of receptor affinity for two of Applicants' claimed compounds. However, in section 5, Declarant states that the compounds of the prior art possess high affinity for somatostatin receptors. Accordingly, the evidence of receptor affinity would appear to be evidence of expected results rather than of unexpected results.

5. Claims 6 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

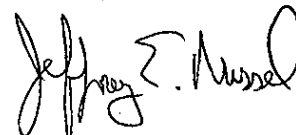
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

PLEASE NOTE: Sometime on or around January 6, 2004, the examiner will be moving to the new USPTO headquarters. At that time, the examiner's phone number will change to (571) 272-0969. After January 6, it is recommended that Applicants attempt to contact the examiner at the new phone number if they are unable to reach him using the old number.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
December 31, 2003